



## Summary of Studies Supporting USDA Product Licensure

Establishment Name	Boehringer Ingelheim Animal Health USA Inc.
USDA Vet Biologics Establishment Number	124
Product Code	1185.23
True Name	Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza 3-Respiratory Syncytial Virus Vaccine, Killed Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Triangle 4 + Type II BVD - Zoetis Inc. Triangle 5 - Boehringer Ingelheim (Canada) Ltd. Triangle 5 - No distributor specified
Date of Compilation Summary	April 10, 2019

**Disclaimer: Do not use the following studies to compare one product to another. Slight differences in study design and execution can render the comparisons meaningless.**

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Bovine Virus Diarrhea (BVD)
<b>Study Purpose</b>	Demonstration of efficacy against BVD Type 1 (respiratory disease)
<b>Product Administration</b>	
<b>Study Animals</b>	Bovine
<b>Challenge Description</b>	BVD isolate NY-1, Type 1b
<b>Interval observed after challenge</b>	
<b>Results</b>	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
<b>USDA Approval Date</b>	November 20, 1996

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Bovine Virus Diarrhea (BVD)
<b>Study Purpose</b>	Demonstration of efficacy against BVD Type 2 (respiratory disease)
<b>Product Administration</b>	
<b>Study Animals</b>	Bovine
<b>Challenge Description</b>	BVD strain IAF 103/BT-4A-2, Type 2a
<b>Interval observed after challenge</b>	
<b>Results</b>	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
<b>USDA Approval Date</b>	July 14, 2003

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Infectious Bovine Rhinotracheitis (IBR)
<b>Study Purpose</b>	Demonstration of efficacy against IBR (respiratory disease)
<b>Product Administration</b>	
<b>Study Animals</b>	Bovine
<b>Challenge Description</b>	
<b>Interval observed after challenge</b>	
<b>Results</b>	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. Study data, however, are no longer available.
<b>USDA Approval Date</b>	November 20, 1996

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Bovine Parainfluenza Type 3 (PI <sub>3</sub> )
<b>Study Purpose</b>	Demonstration of efficacy against PI <sub>3</sub>
<b>Product Administration</b>	
<b>Study Animals</b>	Bovine
<b>Challenge Description</b>	
<b>Interval observed after challenge</b>	
<b>Results</b>	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. Study data, however, are no longer available.
<b>USDA Approval Date</b>	November 20, 1996

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Bovine Respiratory Syncytial Virus (BRSV)
<b>Study Purpose</b>	Demonstration of efficacy against BRSV
<b>Product Administration</b>	
<b>Study Animals</b>	Bovine
<b>Challenge Description</b>	
<b>Interval observed after challenge</b>	
<b>Results</b>	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
<b>USDA Approval Date</b>	September 7, 1999

<b>Study Type</b>	Safety
<b>Pertaining to</b>	All fractions
<b>Study Purpose</b>	To demonstrate safety under field conditions
<b>Product Administration</b>	
<b>Study Animals</b>	Bovine including pregnant animals at all stages of gestation
<b>Challenge Description</b>	
<b>Interval observed after challenge</b>	
<b>Results</b>	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
<b>USDA Approval Date</b>	January 22, 1998